

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

REC'D 02 MAR 2005


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Applicant's or agent's file reference 15640PCT00	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00820	International filing date (day/month/year) 28.11.2003	Priority date (day/month/year) 29.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M25/00		
Applicant COLOPLAST AS ET AL.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.  
  
☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
These annexes consist of a total of 1 sheets.

## 3. This report contains indications relating to the following items:

- ☒ Basis of the opinion
- ☐ Priority
- ☐ Non-establishment of opinion with regard to novelty, inventive step and Industrial applicability
- ☐ Lack of unity of invention
- ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Certain documents cited
- ☐ Certain defects in the international application
- ☐ Certain observations on the international application

Date of submission of the demand  07.06.2004	Date of completion of this report  03.03.2005
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31-70-340-2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Kousouretas, I  Telephone No. +31 70 340-2449



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/DK 03/00820**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

**Description, Pages**

1-7 as originally filed

**Claims, Numbers**

2-21 as originally filed

1 filed with telefax on 24.02.2004

**Drawings, Sheets**

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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International application No. **PCT/DK 03/00820**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	8-20
	No: Claims	1-7,21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/DK 03/00820

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The use of a 'sleeve attached to the catheter' (claim 1) has not been disclosed in the priority document, therefore the priority is not valid as far as the above feature is concerned. Thus, the document US2003018293 cited in the ISR as a P document should be considered as published 'in time' for considering novelty and inventive step of claim 1.

2. Reference is made to the following documents:

D1: US-A-3 934 721 (JUSTER ROBERT W ET AL) 27 January 1976 (1976-01-27)

D2: US-A-4 178 735 (JACKSON KNUTE D) 18 December 1979 (1979-12-18)

D3: US 2003/018293 A1 (TANGHOJ ALLAN ET AL) 23 January 2003 (2003-01-23)

**3 INDEPENDENT CLAIMS**

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D3 discloses (see paragraph 94 and figures 16-18, the references in parentheses applying to this document):

A catheter with a conduit for draining body fluid from at least one inlet opening (4) in a proximal, insertable, end (42) of the catheter to at least one outlet opening (52), said catheter comprising first and second parts (42,44), wherein the first part forms the proximal end, and the second part forms a distal end, the first and second parts having different cross-sectional size and/or shape and being joined in a fixed connection, the first part is at least partly encapsulated in a sleeve (46) which is attached to the catheter to leave at least a portion of the second part of the catheter uncovered (figure 18) by the sleeve, wherein the sleeve is attached to the catheter in a seal forming a liquid or bacteria tight barrier.

**INTERNATIONAL PRELIMINARY  
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3.2 Claim 21 is not new in view of D1 (see column 1, line 65- column 2, line 62, column 3, line 46- column 4, line 3 and figures).

3.3 Claim 21 is also not new in view of D2 (see search report).

4. Dependent claims 2-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step. See for example:

D3 (search report) for claims 2-7

D1 (column 1, line 65- column 2, line 62, column 3, line 46-column 4, line 3 and figures) for claims 10,14-17,19,20

Finally claims 8,9,11-13 and 18 are obvious design options for the skilled person with no surprising or unexpected effect.

24 FEB 2005

APPLICATION NO: PCT/DK03/00820  
APPLICANT: COLOPLAST  
TITLE: A CATHETER  
OUR REF: 15640PCT00

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**NEW CLAIMS - FEBRUARY 2005 - MARKED UP VERSION**

1. A catheter with a conduit for draining body fluid from at least one inlet opening in the a proximal, insertable, end of the catheter to at least one outlet opening, said catheter comprising first and second parts, wherein the first part forms the proximal end, and the
- 10 second part forms a the distal end, the first and second parts having different cross-sectional size and/or shape and being joined in a fixed connection, ~~characterized in that~~ and the first part is at least partly encapsulated in a sleeve which is attached to the catheter to leave at least a portion of the second part of the catheter uncovered ~~thereby~~ by the sleeve,
- 15 characterized in that the sleeve is attached to the catheter in a seal forming a liquid or bacteria tight barrier.

AMENDED SHEET  
IPEA/EP

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